

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ALLERGAN, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., et al.,

Defendants.

Civil Action No. 2:15-cv-1455 WCB

LEAD CASE

JURY TRIAL DEMANDED

**ALLERGAN, INC.'S RESPONSE TO MYLAN PHARMACEUTICALS INC. AND
MYLAN INC.'S MOTION TO COMPEL**

Mylan's motion to compel production of the Apotex settlement agreement¹ overlooks the fact that the agreement itself precludes Allergan from producing it—as Allergan has repeatedly told Mylan. And the confidentiality provisions to which Allergan and Apotex agreed during settlement negotiations should not be discarded lightly—that provision, and others like it, encourage settlement and reflect the policy concerns underlying Federal Rule of Evidence 408. Ignoring that Allergan is prohibited by the terms of the Apotex agreement from producing it, Mylan overstates any possible relevance of the agreement to this case while improperly minimizing the serious confidentiality concerns that accompany its production. Any potential relevance—and there is little, if any—is outweighed by the risk of unfair prejudice to Allergan.

The relevance of the Apotex agreement to the issues in this case is marginal at best, and Mylan's real reason for seeking it is not so that it can use it for the purported reasons cited in its

¹ In its motion, Mylan also seeks production of Allergan's settlement agreement with Argentum Pharmaceuticals LLC. (Dkt. No. 210 at 1 n.1.) This issue is not ripe for the Court's consideration—Mylan demanded its production for the first time just one day before filing its motion to compel. To the extent the Court does reach the issue, it should deny Mylan's request for the same reasons outlined in this response.

brief, but so it can use it to gain unfair leverage in settlement negotiations. Mylan's intent to use the agreement for this improper purpose is made clear by Mylan's refusal to consider a potential compromise under which Allergan would produce the agreement on an Outside Counsel's Eyes Only basis (subject to agreement from Apotex) and with the further restriction that anyone viewing it could have no involvement in settlement negotiations.

Moreover, if the Apotex agreement were truly relevant and necessary for Mylan to "effectively litigate its case," as Mylan now suggests, then Mylan would have diligently pursued its production rather than intermittently raising the issue over an eight-month period. But it did not. Contrary to Mylan's characterization of this dispute in its brief, Allergan has not been "stonewalling" Mylan on this issue—Mylan has let the issue languish for months at a time.

The Court should not require that Allergan threaten its confidentiality obligations to Apotex and produce the agreement so that Mylan can use it for improper purposes. Therefore, Allergan respectfully requests that the Court deny Mylan's motion.

I. BACKGROUND

In this Hatch-Waxman case, Allergan has sued Mylan, along with a number of other generic drug companies, for infringement of its patents covering its ophthalmic product Restasis®. On December 15, 2015, Allergan entered into a settlement agreement with then-defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"). Nearly four months later, on April 4, 2016, Mylan sought production of the Apotex settlement agreement, generally claiming relevance to the "claims and defenses at issue in this case." (Dkt. 210, Ex. 1.)

Allergan responded that Mylan had not shown the agreement to be relevant, and further that the agreement itself contains a confidentiality clause that prevents Allergan from disclosing it. (Dkt. 210, Ex. 5 at 8.) After a few weeks of back-and-forth correspondence, on May 19, 2016, Allergan reiterated its position that the Apotex agreement is irrelevant and did not agree

produce it. (*Id.* at 5.) Despite ongoing communication between the parties on other case-related issues, Mylan did not resurrect its production request until July 7, 2016—after nearly two months of complete silence on the issue. In response, Allergan again stood by its initial position that the agreement is not relevant and pointed out that Mylan had yet to cite a single Hatch-Waxman case in which such an agreement was subject to production. (*Id.* at 4.)

Less than two weeks after Mylan identified the authority on which it was relying, Allergan attempted to arrange a meet-and-confer on the issue. (*Id.* at 1-2.) Mylan never responded. Indeed, it was not until November 10, 2016—another three months later—that Mylan raised the issue again. During a meet and confer between the parties on November 30, 2016—which was initiated by Allergan on a different issue—Allergan proposed a potential compromise that it hoped would avoid motion practice: it would try to get Apotex’s agreement that it could produce the agreement on an “Outside Attorneys’ Eyes Only” basis on the condition that persons given access to the agreement could not participate directly or indirectly in settlement negotiations between Mylan and Allergan. (Ex. A at 1.) Mylan rejected Allergan’s compromise and on December 2, 2016 indicated its intention to file a motion compel with the Court.

II. ARGUMENT

A. Mylan Seeks Production of the Agreement for an Improper Purpose That Is Prejudicial to Allergan and Contrary to the Policy of Encouraging Settlement

Even if the Apotex settlement agreement were marginally relevant—and as discussed below, it is not—Mylan’s conduct in seeking the Apotex agreement makes clear that its true purpose in obtaining the agreement is to gain improper leverage in settlement negotiations with Allergan. Production of the agreement would be highly prejudicial to Allergan.

Allergan entered into the settlement agreement with Apotex in December 2015, but Mylan did not seek its production until April 2016, despite being aware of the settlement at the time it occurred. And then, instead of diligently pursuing the issue, Mylan pressed for its production only intermittently over the next eight months. After Mylan's first request for the agreement, the parties engaged in a back-and-forth exchange on the issue for a little over a month. In May, Allergan reiterated its position that the Apotex agreement is not relevant and would not agree to its production. Mylan did not promptly respond. Instead, after nearly *two months* of silence on the issue, Mylan sent a letter to Allergan in July rehashing the same arguments it made before about the purported relevance of the agreement. Mylan also never responded to Allergan's attempt to meet and confer on the issue in August, and instead waited another *three months* to broach the topic again. Mylan's conduct belies its true intent: if this agreement is as relevant and necessary as Mylan now claims, then Mylan would have consistently and promptly sought its production.

Mylan also glosses over the fact that Allergan attempted to reach a compromise that would reduce the risk of prejudice to Allergan, under which Allergan could produce the agreement subject to conditions. Allergan offered a potential compromise (subject to seeking agreement from Apotex), wherein it would produce the Apotex agreement so long as it was designated on an "Outside Attorneys' Eyes Only" basis, and that persons given access to the agreement would not participate in settlement negotiations with Allergan. (Ex. A at 1.) Despite Mylan's claims otherwise, Allergan's proposed conditions are reasonable under these circumstances: Mylan would have access to the agreement for the purported purpose of building its case, and Allergan and Apotex would have some additional protection against misuse of the agreement by Mylan. If Mylan truly wanted the agreement only for its stated purposes, it would

have accepted these conditions. Mylan's refusal to accept to Allergan's compromise underscores Mylan's ulterior motive in seeking this production—to gain leverage in settlement negotiations with Allergan and gain an advantage over its competitor Apotex.

In a Hatch-Waxman case such as this one, all the defendants are similarly situated—they are all seeking to come on the market with a generic version of Allergan's Restasis® product. Forcing a Hatch-Waxman Plaintiff to show all remaining defendants in the same or related cases the exact terms under which an earlier defendant settled would put the plaintiff in an unfair and untenable position in later settlement negotiations. Hatch-Waxman plaintiffs, like Allergan, would be in the position of negotiating any later settlement agreement with their cards “face up,” a fact that would discourage settlement. Further, requiring Allergan to break its confidentiality agreement here and allowing Mylan to obtain the Apotex agreement would directly conflict with the policy concerns underlying Federal Rule of Evidence 408 and the desire to encourage settlement.

B. The Apotex Agreement Is of Marginal Relevance at Best

Even if its disclosure would not be highly prejudicial to Allergan, the settlement agreement has marginal, if any, relevance to any issues in this case. Settlement agreements are relevant primarily to damages issues but, because this case was brought under the Hatch-Waxman Act and there has not been any generic product launch, there is no claim for damages here. Mylan alleges that the agreement is relevant to issues of secondary considerations, injunctive relief, and potential patent misuse, but none of those arguments holds water.

The Apotex agreement is not relevant to secondary considerations of nonobviousness, such as commercial success, because Allergan does not intend to rely on the agreement as evidence of nonobviousness. Instead, as highlighted in its interrogatory responses, Allergan intends to rely on prescription data and sales revenues of Restasis® to demonstrate the

commercial success of its product. Mylan cites *Datapoint Corp. v. Picturitel Corp.*, No. 3:93-CV-2381, 1998 WL 51356, at *2 (N.D. Tex. Jan. 23, 1998) for the proposition that courts have held that settlement and license agreements are relevant to a claim of commercial success. But in that case, the Court noted that “[p]atentees like Datapoint often use license agreements obtained in settlement of litigation to show the commercial success and nonobviousness of a patent.” Unlike in *Datapoint*, Allergan does not intend to use the Apotex agreement to show nonobviousness, so the agreement is not relevant for that purpose.

The Apotex agreement is similarly not relevant to Allergan’s entitlement to injunctive relief. In the event Allergan prevails, one of Allergan’s remedies is provided by the Hatch-Waxman Act itself: an order that FDA approval of Mylan’s ANDA be no earlier than the expiration date of Allergan’s patents and a permanent injunction barring Mylan from selling its generic version of Restasis®. 35 U.S.C. § 271(e)(4)(A), (B). Allergan’s settlement with Apotex has no bearing on its entitlement to this statutory remedy, and Mylan cites no cases that address the relevance of a settlement agreement to injunctive relief in the context of a Hatch-Waxman case. Moreover, Mylan’s assertion that the confidential terms of the Apotex agreement are relevant to irreparable harm is incorrect. The only arguable relevance to irreparable harm, if any, is the existence of the agreement itself—the fact that Allergan entered into a license agreement with Apotex. The confidential terms of the agreement, however, are of no relevance and Mylan has not shown otherwise.

Finally, Mylan’s patent misuse argument is nothing more than a fishing expedition: Mylan has not—and cannot—point to anything that even suggests anticompetitive action. Moreover, Mylan has not asserted a patent misuse claim in this case. The pleadings have been closed for over six months and Mylan has recently filed a motion for leave to amend its answer

and counterclaims, but did not add a patent misuse claim. (Dkt. Nos. 229, 230.) The Court should not allow discovery on the mere speculation that the Apotex agreement unduly restricts competition.

C. Allergan Is Precluded from Producing the Apotex Agreement

By its own terms, the Apotex settlement agreement that Mylan wants to force Allergan to produce prevents Allergan from producing it. As part of the agreement with Apotex, Allergan entered into a confidentiality agreement according to which Allergan cannot disclose the settlement agreement to third parties without Apotex's consent. Allergan approached Apotex in August with Mylan's request for production and Apotex refused to give consent. (Ex. B.) Apotex requested that Allergan take "all reasonable measures to prevent or limit disclosure of the agreement," including opposing any motion to compel by Mylan, and requesting production on an outside counsel only basis. (Ex. B.) Allergan cannot simply breach its agreement with Apotex and give the settlement agreement to Mylan over Apotex's objection.

Mylan knows this, but chose to misstate Allergan's position as relating to the sufficiency of the protective order in this case instead of citing to Allergan's express obligations under the Apotex agreement. The fact that a protective order has been entered in this case is immaterial to the issue—it does not alleviate Allergan's contractual duty to Apotex not to disclose confidential settlement terms.

III. CONCLUSION

Mylan should not be allowed to gain improper settlement leverage over Allergan under the guise of a motion to compel relevant evidence. The Apotex agreement is of minimal, if any, relevance, and the potential risk of unfair prejudice to Allergan is significant. Allergan and Apotex agreed to confidentiality restrictions that prohibit the production of the settlement

agreement, and those restrictions should not be lightly disturbed. The Court should deny Mylan's motion.

Dated: December 23, 2016

Respectfully submitted,

FISH & RICHARDSON P.C.

By: /s/ Susan Morrison Coletti

Jonathan E. Singer
(CA Bar No. 187908, MN Bar No. 283459)
LEAD ATTORNEY
singer@fr.com
Juanita R. Brooks (CA Bar No. 75934)
brooks@fr.com
12390 El Camino Real
San Diego, CA 92130
Telephone: 858-678-5070
Facsimile: 858-678-5099

Michael J. Kane (MN Bar No. 0247625)
kane@fr.com
Deanna J. Reichel (MN Bar No. 0326513)
reichel@fr.com
Joseph A. Herriges (MN Bar No. 390350)
herriges@fr.com
60 South Sixth Street, #3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Douglas E. McCann (DE Bar No. 3852)
dmccann@fr.com
Susan Morrison Coletti (DE Bar No. 4690)
coletti@fr.com
Robert M. Oakes (DE Bar No. 5217)
oakes@fr.com
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
Telephone: (302) 652-5070
Facsimile: (302) 652-0607

J. Wesley Samples (OR Bar No. 121784)
samples@fr.com
1425 K Street, NW, 11th Floor
Washington, DC 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

T. John Ward, Jr.
State Bar No. 00794818
E-mail: jw@wsfirm.com
Wesley Hill
State Bar No. 24032294
E-mail: wh@wsfirm.com
Claire Abernathy Henry
State Bar No. 24053063
E-mail: claire@wsfirm.com
WARD, SMITH & HILL, PLLC
1507 Bill Owens Parkway
Longview, Texas 75604
Telephone: (903) 757-6400
Facsimile: (903) 757-2323

COUNSEL FOR PLAINTIFF
ALLERGAN, INC.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 23rd day of December, 2016.

/s/ Susan Morrison Coletti
Susan Morrison Coletti